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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/440,462	11/15/1999	WALID NAJIB ABOUL-HOSN	032301-047	2975

7590 02/25/2003

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 02/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

600/16

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/440,462	ABOUL-HOSN ET AL.
Examiner	Art Unit	
Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 16 December 2002.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 24-36 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-23 and 37-49 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims 24-36 drawn to an invention non-elected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Drawings***

2. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 19-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/021,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because in order to use a pump to convey blood from one region of the heart to

another, some sort of device (i.e., controller or sensor) is needed to control or regulate the pump speed or flow rate. Claim 1 of copending Application No. 10/021,549 recite the use of a cradle for supporting the beating heart. Claim 19 of Application 09/440,462 recites that the heart is lifted or displaced during surgery. It will be obvious to use a cradle, or similar device, in order to lift, support, or displace the beating heart while performing surgery.

5. Claim 37 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,395,026 B1 and claim 15 of copending Application No. 10/021,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 37 is a slightly broader version of claim 2 of U.S. Patent No. 6,395,026 B1 and claim 15 of copending Application No. 10/021,549. Claim 2 of U.S. Patent No. 6,395,026 B1 and claim 15 of copending Application No. 10/021,549 recite the use of a cradle for supporting the beating heart. Claim 37 of Application 09/440,462 recites that the heart is lifted or displaced during surgery. It will be obvious to use a cradle, or similar device, in order to lift, support, or displace the beating heart while performing surgery.

#### *Claim Objections*

6. Claim 1 is objected to because of the following informalities: in line 10, a comma (",") should be inserted after "of the heart" (see for example line 12 of claim 48). Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 23, 37-39, 43, and 44 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Phillips (US 4,955,856). Phillips discloses a system comprising one or two cannula, one or two pump systems, and with the same orientation (i.e., cannula goes first through tricuspid valve, then through pulmonary valve, then through pulmonary artery) as in claims 23, 37-39, 43, and 44 (see Figure 3; see column 2, lines 45-48; column 3, lines 1-8; see entire document).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-23 and 37-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US 4,955,856) in view of Jarvik (US 5,376,114) and Koros et al. (US 5,167,223). Phillips discloses a system comprising one or two cannula and one or two pump systems as claimed in the present application (see 102 rejection above).

Phillips does not disclose the pump as been coupled to a controller. However, Jarvik teaches a pump coupled to a microprocessor-based controller in order to regulate the flow and pressure of the blood flowing through the cannula (see column 3, lines 29-55). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a pump coupled to a controller, as taught by Jarvik, to the system of Phillips, in order to regulate the flow and pressure of the blood flowing through the cannula.

Phillips does not disclose a priming volume of not greater than about 1000 ml. However, Jarvik teaches a pump/cannula system that reduces the combined priming volume to the point that it could be essentially zero in order to aid in simplify management of heart function during the surgical procedure (see column 1, lines 58-64; column 6, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a pump/cannula system that reduces the combined priming volume to the point that it could be essentially zero, as taught by Jarvik, to the system of Phillips, in order to aid in simplify management of heart function during the surgical procedure.

Phillips does not disclose the use of a cradle adapted to support the heart while the surgery is performed. However, Koros et al. teach a cradle (i.e., net) adapted to support the heart in order to provide better access to the heart for the surgeon (see Figure 1; column 3, lines 48-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a cradle to support the heart while performing a surgical procedure, as taught by Koros et al., to the system of Phillips, in order to provide better access to the heart for the surgeon.

*Response to Arguments*

11. Regarding 102(b) rejection over Phillips '856, and 103(a) rejection over Phillips '856 in view of Jarvik '114 and Koros '223, Applicants' arguments filed December 16, 2002 have been fully considered but they are not persuasive. Applicants argue "none of the cited references, alone or in combination, teach or suggest a device having first and second flow paths adapted to provide blood intake from a first location in an atrium or blood vessel and provide blood output at a second location in a blood vessel, thereby bypassing blood inflow from the right ventricle and the left ventricle. Examiner respectfully disagrees.

Figure 3 shows a cannula having inflow/outflow paths and extending through the vena cava or right atrium, passing through the tricuspid valve and through the pulmonary valve (= bypassing blood flow from the left and right ventricles), and reaching the pulmonary artery. Figure 3 also shows another cannula having inflow/outflow paths and extending through the pulmonary vein or left atrium, passing through the bicuspid valve and through the aortic valve (= bypassing blood flow from the left and right ventricles), and reaching the aorta (see column 3, lines 20-24).

*Conclusion*

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

----- A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.); first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



JGB

February 22, 2003



David H. Willse  
Primary Examiner